Medivir
Q3-2016 Conference call
10 November, 2016

Niklas Prager CEO
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MEDIVIR

A research-based pharmaceutical company with focus on oncology and infectious diseases

Q3 Highlights

Continued progress in R&D including partnered projects

- Entered into a licensing agreement with Trek Therapeutics for the exclusive rights to develop and commercialise MIV-802 globally, excluding China, Taiwan, Hong Kong and Macau
- Following DMC review of unblinded safety data from MIV-711-201, the study was given the go-ahead to continue and the first patient was enrolled in the open label phase IIa study, MIV-711-202
- Updated interim data from the ongoing phase IIa study of simeprevir, odalasvir and AL-335 showed 100% SVR12 after eight or six weeks of treatment in treatment naive GT1 patients

Global Net Sales of OLYSIO® of USD 21m generating a royalty of SEK 12m

- Nordic Olysio sales reached SEK 1.3m

Significant events after third quarter

- **Medivir focuses exclusively on oncology and reorganizes to signifcantly reduce the cost structure**
- **Enrolment into MIV-711-201 is completed and the second meeting of the DMC again recommended that the trial should go ahead**
- **Divestment of the pharmaceutical company, BioPhausia (Nordic Brands) to Karo Pharma**
- **Our nucleotide polymerase inhibitor for the treatment of liver cancer, MIV-818, enters non-clinical development**
- **Strengthening of the R&D pipeline by signing an agreement to acquire two clinical phase oncology programmes**

Financial summary

Summary of Group´s figures (SEK m)	Q3		Nine Months	
	2016	2015	2016	2015
Net turnover	67.8	111.5	224.1	573.2
Gross profit	48.7	90.2	159.0	487.9
EBITDA	-35.6	1.3	-108.0	190.9
Operation profit (EBIT)	-44.4	-13.1	-133.3	159.2
Profit/loss before tax	-40.4	-13.3	-122.0	155.0
Profit/loss after tax	-50.4	-10.5	-130.6	120.3
Operating margin, %	-65.5%	-11.7%	-59.5	27.8
Basic earnings per share	-1.87	-0.39	-4.85	4.14
Diluted earnings per share	-1.87	-0.39	-4.85	4.11
Net worth per share	48.99	55.36	48.99	54.36
Return on Equity	-11.5%	-0.9%	-11.8%	8.9%
Cash flow from operating activites	-37.0	75.4	-110.5	345.0
Liquid assets and ST investments	955.0	1 118.1	955.0	1 118.1
R&D spending/total opex, %	75.9%	68.1%	73.4%	63.3%

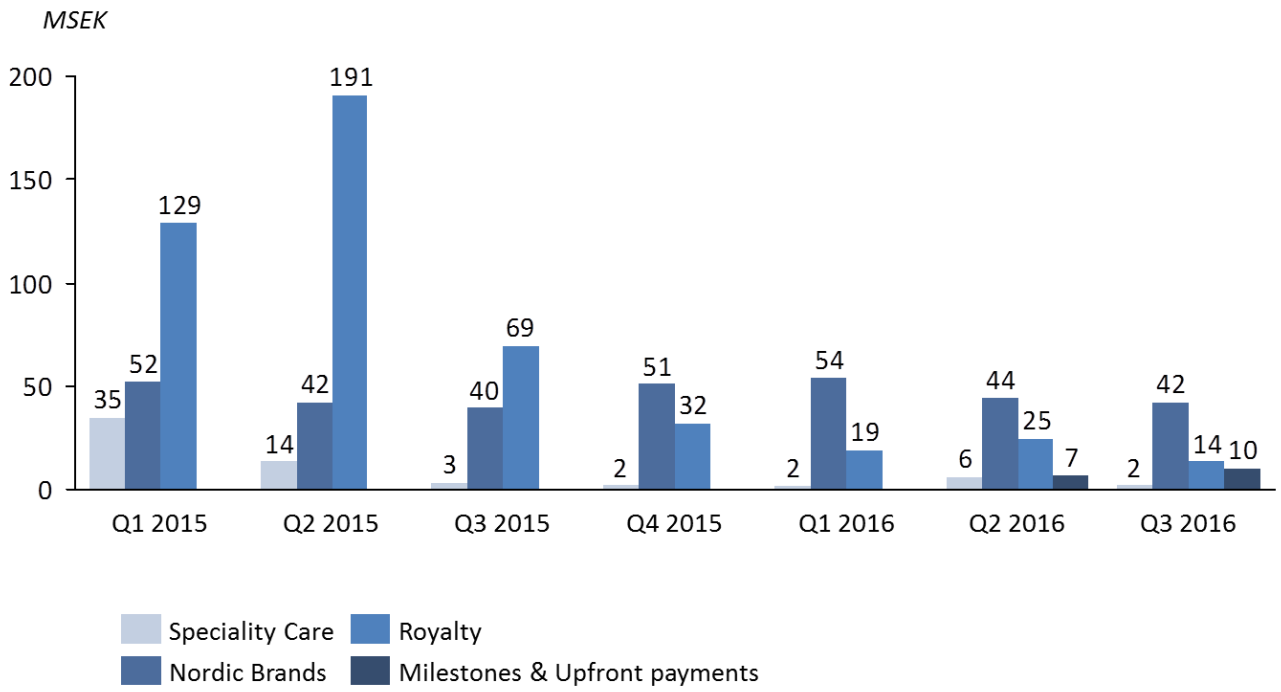
Q3 Net turnover

- Net turnover totalled SEK 67.8m (111.5m), of which SEK 12.4m (69.0m) comprised third quarter royalties for simeprevir.
- Revenue from Medivir's own pharmaceutical sales totalled SEK 44.0m (42.5m), of which 42.1 million (39.0m) was generated by the Nordic Brands portfolio. The Innovative Specialty Care portfolio achieved sales of 1.9 million (3.6 m).

Q3 Key figures

- Operational loss (EBIT) was -44.4m (-13.1)
- The loss after tax was SEK -50.4m (-10.5m)
- Basic and diluted earnings per share totalled SEK -1.87 (-0.39) and SEK -1.87 (-0.39), respectively
- The cash flow from operating activities amounted to SEK -37.0m (75.4m)
- Liquid assets and ST investments amounted to SEK 955.0m (1 118.1)

Breakdown of net turnover



Pharmaceutical sales

- Nordic net sales totalled SEK 44.0 million, of which SEK 1.9 million derived from sales of OLYSIO®
- Nordic Brands sales totaled SEK 42.1 million (39.0), representing 7.9% growth vs. same quarter last year. Seasonal variations are driven by Mollipect sales, which are driven by the timing and intensity of the flu season

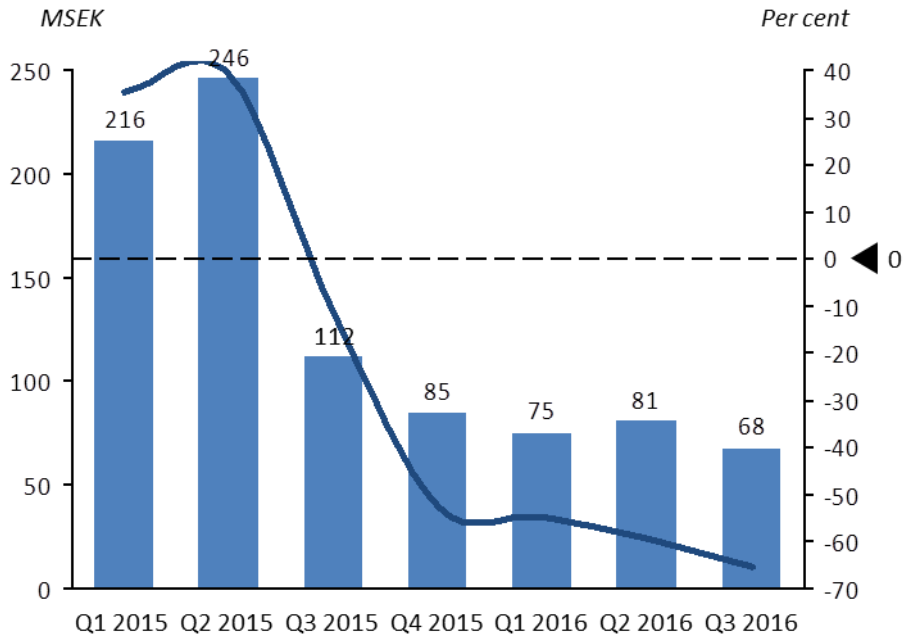
Royalties and Milestones

Royalty income totaled SEK 13.5m (69.0), a decline of SEK 55.5m

- Janssen´s global net sales of simeprevir amounted to USD 21m (79m), whereof US net sales were USD 13m and RoW USD 8m

SEK 10.3m in upfront payments and compund inventory were received, following outlicensing of MIV-802

Operating income and margin



Gross Profit

- The gross profit amounted to SEK 48.7m, corresponding to a decrease of SEK 41.5m and equating a gross margin of 71.8% (80.9%), explained by the decline in royalties

Operating Expenses

- Selling expenses decreased by SEK 12.6m compared to the same quarter last year
- Administrative expenses decreased by SEK 4.2m.
- Research and development costs increased by SEK 0.3m, primarily as a result of the ongoing phase IIa study of MIV-711
- Other operating income/expenses are positive amounted to SEK 0.6m (6.9m)
- Overall, operating expenses totaled SEK -93m (-103.3 m), corresponding to a decrease of SEK 10.3m

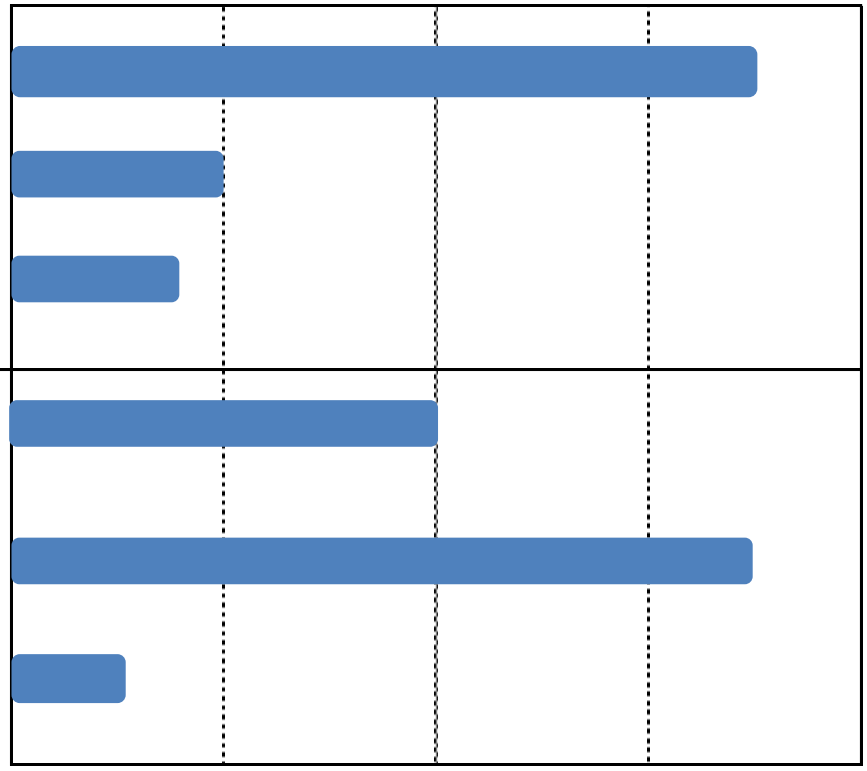
Operating Loss

- Operating loss totaled SEK -44.4m (-13.1), corresponding to a decrease of SEK 31.3m

Research & Development

Medivir R&D pipeline

Disease area/Project	Discovery	Preclinical	Phase I	Phase II
Osteoarthritis MIV-711, cathepsin K inhibitor				
Hepatocellular Carcinoma MIV-818, nucleotide DNA polymerase inhibitor				
RSV-infection Fusion protein inhibitor				
Hepatitis C MIV-802, nucleotide NS5B polymerase inhibitor*				
Hepatitis C 3DAA FDC AL-335+odalasvir+simeprevir**				
HIV-infection protease inhibitor**				



* Partner Trek Therapeutics

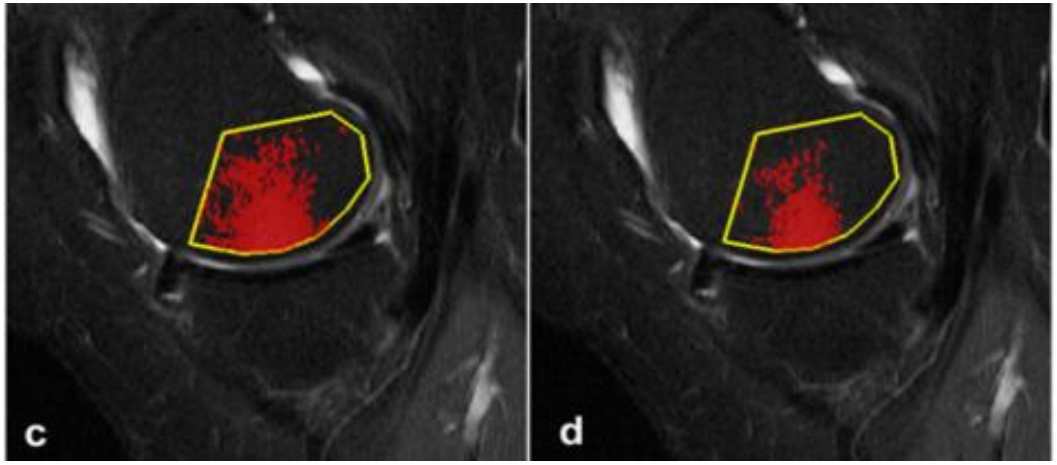
** Partner Janssen

Protease inhibitor portfolio: MIV-711

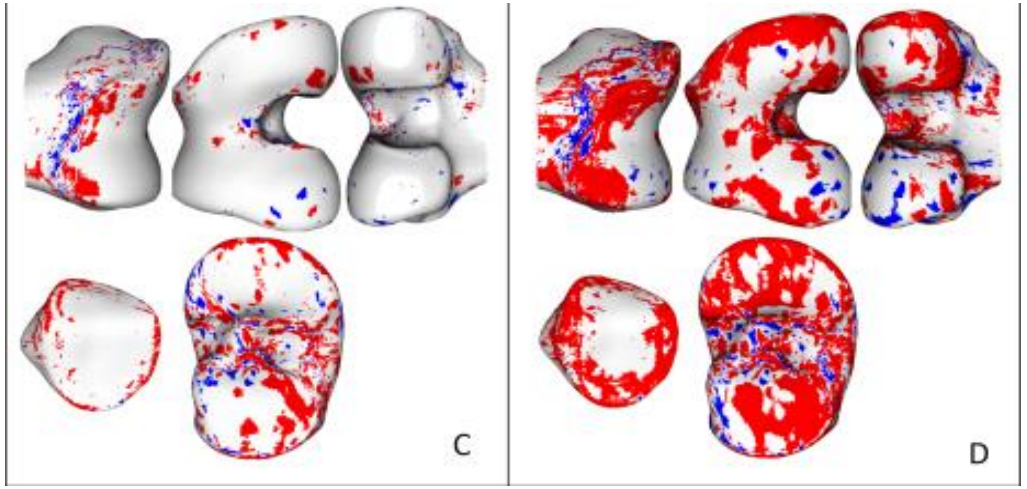
MIV-711 201

- The phase IIa study of MIV-711 in patients with moderate knee osteoarthritis was initiated early in the first quarter

  www.clinicaltrials.gov/ct2/show/NCT02705625
- Two meetings of the DMC have reviewed unblinded safety data from the study and concluded that the study should go ahead
- Enrollment in the study is complete, and data from the study are expected towards the end of the 3Q 2017
- MIV-711-202, an extension study for patients completing MIV-711-201, was initiated in September



Picture modified from: Nielsen FK et al. BMC Musculoskeletal Disorders 2014, 15:447



Picture modified from: Bowes MA, et al. Ann Rheum Dis 2015;74:519–525

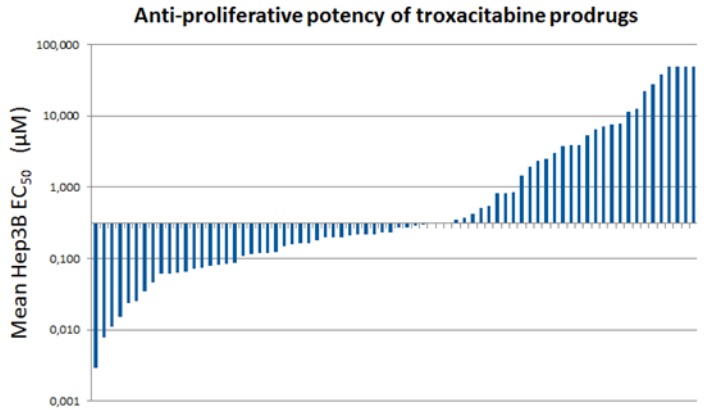
MIV-818: A nucleotide prodrug for liver cancer

Project Background:

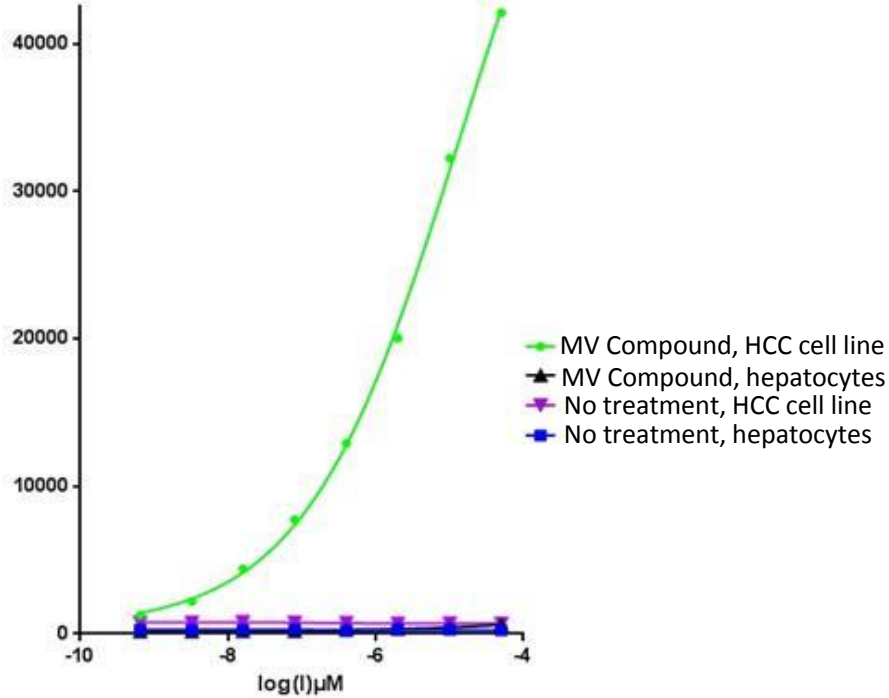
- Starting point is troxacitabine, which is active in preclinical cancer models, but failed in clinic due to systemic dose limiting toxicities
- Not a substrate for enzymes conferring resistance to other nucleoside analogues
- Novel compounds synthesized using Medivir technology to enable directed delivery to the liver
  - Aim to improve activity and safety

MIV-818:

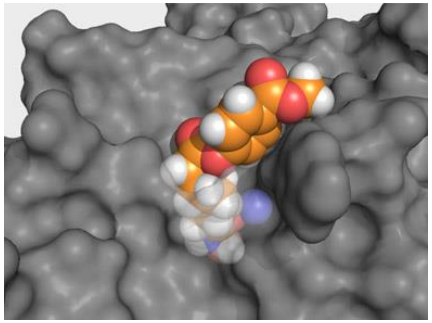
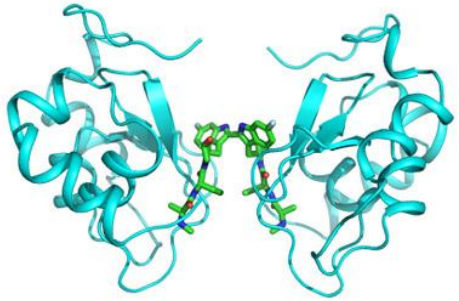
- Prodrug with enhanced activity against HCC cell lines
- Selective for HCC cells relative to non-cancerous human hepatocytes, have been identified
- Greater than 100-fold improved delivery to the liver compared to the parent nucleoside
- Synergistic with sorafenib, the current standard of care for advanced HCC
- Project presented at the 10th annual meeting of the International Liver Cancer Association in September: http://www.medivir.se/v5/images/pdf/2016/ILCA-2016-Poster-P035_HCC-nuc-Albertella-Bethell-final.pdf



Marker of DNA Damage response



Acquisition of innovative therapies in key areas of unmet medical need

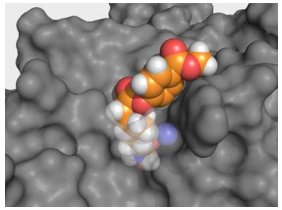
Compound	Clinical Stage	Indication	Mechanism
remetinostat 	Phase II	Early stage cutaneous T-cell lymphoma (CTCL, an orphan hematologic cancer)	Topical, skin-directed inhibitor of histone deacetylases (HDACs)
birinapant 	Phase I	Various solid tumors (combination with Keytruda) MERCK	Bivalent second mitochondrial activator of caspases (SMAC) mimetic, an inhibitor of apoptosis proteins (IAP) inhibitor
	Phase II	High-grade serous carcinomas (including ovarian cancer) UCLA	

Link to Medivir platform:
HDACs are a group of enzymes closely related to proteases

Link to Medivir platform: Peptidomimetic, like simeprevir, and with a strong link to Medivir's current interests in protein ubiquitylation

Remetinostat CTCL clinical trial results promising to date with phase III program expected to start in 2H 2017

remetinostat



Clinical Stage	Indication	Mechanism
Phase II	Early stage cutaneous t-cell lymphoma (CTCL, an orphan hematologic cancer)	Skin-directed histone deacetylase (HDAC) inhibitor

Interim phase II data in highly treatment-experienced population demonstrate efficacy profile appropriate for early stage CTCL

- Open-label Phase II design facilitated Medivir's review of the trial data
- Complemented by extensive discussions of the data with CTCL physicians

Safety and tolerability profile consistent with the skin-specific activity of the drug

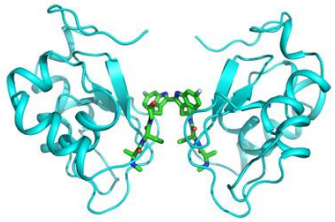
- No AEs typically associated with systemic HDAC inhibitors were observed

- Planning underway for Phase III start in 2H 2017 with potential for launch in 2021
- Phase III program expected to be of modest size and cost

As a topical, skin-specific HDAC inhibitor, remetinostat has the potential to be efficacious and have an improved safety profile considering other available treatments

Combination trial with Keytruda designed to demonstrate enhanced efficacy of PD-1 inhibitors with birinapant across multiple solid tumor types

birinapant



Clinical Stage	Indication	Mechanism
Phase I	Various solid tumors (combination with Keytruda)	Bivalent, second mitochondrial activator of caspases (SMAC) mimetic, an inhibitor of apoptosis proteins (IAP) inhibitor

MERCK

Immuno-oncology market dynamics

- **Keytruda: a key part of the immuno-oncology revolution that's transforming care for cancer patients**
  - Approvals in melanoma, NSCLC and HNSCC
- **PD-1 inhibitor revenues now $3.2B annually(1) and growing with additional treatments in late-stage trials**
- **Despite immunotherapy breakthroughs, significant unmet need remains**
  - While some patients derive enormous benefits from the use of a PD-1 antagonist, the benefits can be limited in many patients
  - Identification of combination regimens to enhance the proportion of patients benefitting from IO therapy is a major trend in cancer R&D

Birinapant benefits

Birinapant expected to enhance efficacy of treatment in combination with immuno-oncology drugs

- Enhancement of T-cell and NK-cell function
- Restoration of immune-cell mediated apoptosis

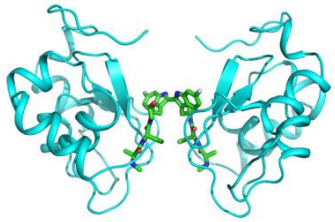
Collaboration with Merck

- Keytruda provided at no cost
- Joint Development Committee to oversee the study

(1) Sources: Merck and Bristol-Myers Squibb financial reports.

Birinapant targets a key unmet medical need in high-grade serous carcinoma

birinapant



Clinical Stage	Indication	Mechanism
Phase II	High-grade serous carcinomas (including ovarian cancer) UCLA	Bivalent, second mitochondrial activator of caspases (SMAC) mimetic, an inhibitor of apoptosis proteins (IAP) inhibitor

Serous carcinoma market dynamics

High-grade serous carcinomas: Group of cancers believed to be derived from cells from the fallopian tube that may present as ovarian, endometrial, tubal or peritoneal cancer

- HGSC is ~70% of ovarian carcinoma, and ~90% of advanced (stage III/IV) ovarian carcinomas
- Treatment with platinum drugs is standard of care, but most relapse within 6-18 months
- There are few options for patients who relapse with chemotherapy remaining the standard of care even for platinum-resistant carcinomas

Ovarian cancer market size overall is US$840M (1)

Birinapant benefits

Platinum-resistant HGSC cells are highly susceptible to birinapant in ~50% of patients

- Tumour-initiating subset of cells resistant to platinum in HGSCs identified by UCLA researchers (2)
- Bioassay available to enable patient selection

UCLA investigator-initiated Phase I/II study planned

- Combination of birinapant with platinum-based chemotherapy in patients with newly diagnosed or recurrent HGSCs
- Strong scientific rationale and highly motivated clinical investigators
- **Medivir to provide birinapant and potentially some financial support, with full rights to generated data**

(1) Source: DR Decision Resources LLC; (2) DM Janzen et al., Nature Commun. (2015) 6:7956

Q&A

www.medivir.com

Ticker: MVIR

Exchange: OMX / NASDAQ

For more information please contact

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